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09/617,099	07/14/2000	Susumu Seino	P19771	5279

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No. 09/617,099	Applicant(s) SEINO ET AL.	
	Examiner Rita Mitra	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3,4 and 6* is/are allowed.

6)☒ Claim(s) *5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

Applicants' amendment and response to office action dated October 22, 2002, filed on January 22, 2003 (paper #14) is acknowledged. Claims 8-10 have been cancelled. Claims 4 and 5 have been amended. Therefore, claims 3-6 are currently pending and are under examination.

Response to Remarks and Arguments

Withdrawal of Rejections

The rejection of claims 8-10 under **35 U.S.C. § 112, first paragraph** is moot in view of Applicants' cancellation of these claims.

The rejection of claims 3, 4 and 6 under **35 U.S.C. § 112, first paragraph** is withdrawn in view of Applicants' amendment to the claims and response and remarks at pages 3-5.

The rejection of claims 8 and 10 under **35 U.S.C. § 112, second paragraph** is moot in view of Applicants' cancellation of these claims.

The rejection of claim 5 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendment and response at page 5.

The rejection of claims 3-6 under **35 U.S.C. § 102** as being anticipated by Wang et al. is withdrawn in view of Applicants' response at page 6.

The rejection of claims 8-10 under **35 U.S.C. § 102** as being anticipated by Wang et al. is moot in view of Applicants' cancellation of the claims.

Rejections under 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 remains/is rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a full length DNA set forth in SEQ ID NO: 2 encoding the protein of SEQ ID NO: 1; does not reasonably provide enablement for the DNA having a

nucleotide sequence with one or more nucleotide substitutions relative to the nucleotide sequence of SEQ ID NO: 2, which encodes a protein of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' reasons and arguments in response to the rejection are fully considered, however they are not found persuasive. The traversal is addressed along with the rejection as set forth below:

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include: 1) the nature of the invention; 2) the breadth of the claims; 3) the predictability or unpredictability of the art; 4) the amount of direction or guidance presented; 5) the presence or absence of working examples; 6) the quantity of experimentation necessary; 7) the state of the prior art; and, 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) The nature of the invention:

The nature of the invention is defined by the claims, which include a mouse DNA encoding a protein set forth in SEQ ID NO: 1 and a mutant thereof. However the specification does not provide the information on the structure and function of the claimed mutants.

2) The breadth of the claims:

The breadth of the claims is broad and encompasses an unspecified amount of variants regarding the DNA's protein products of SEQ ID NO: 1 as biological active variants, which are not specifically described or demonstrated in the specification.

Claim 5, which is directed to a DNA having a nucleotide sequence with one or more nucleotides substituted relative to the nucleic acid sequence set forth in SEQ ID NO: 2. Specification while defining "one or more" indicates at page 5 that several (e.g. 3 or 4) to 10 nucleotides relative to SEQ ID NO: 2 would be modified, and at page 7 specification provides a

general description on how a variety of mutants can be generated. However, the specification fails to provide any specific description of the structure and function of the mutants generated. While the specification in Example (page 14, lines 15-22, Fig. 4), and at page 9, lines 4-16 describes and demonstrates that the full length DNA set forth in SEQ ID NO: 2 encoding the protein of SEQ ID NO: 1 has a property to interact with cAMP-GEFII, there is no disclosure about the biological activities of the claimed mutants.

Regarding claim 5 Applicants assert at page 4 that DNA of amended claim 5 would still have the same amount of nucleotides as that claimed in claim 3, and would encode the protein having SEQ ID NO: 1, and therefore retain the same function. Furthermore, Applicants assert that one of ordinary skill in the art, having both the nucleotide sequence set forth in SEQ ID NO: 2 and using a DNA code table, would be able to practice the claimed invention by substituting nucleotides in the sequence of in the sequence of SEQ ID NO: 2 such that the final protein encoded would still have the amino acid sequence set forth in SEQ ID NO: 1. The arguments are considered but not found persuasive because the amended claim reads "one or more nucleotides substitution relative to the nucleotide sequence of SEQ ID NO: 2, that encodes a protein having the amino acid sequence of SEQ ID NO: 1." The amended claim has further broadened the claim. The invention requires one skilled in the art to locate a region with one or more nucleotides in the DNA sequence of 4804 nucleotides of SEQ ID NO: 2, then generate an unspecified number of mutants by conservative and/or non-conservative amino acid substitution, (using a genetic code Table), then characterize those mutants to determine if they have the property to interact with cAMP-GEFII, However, the specification does not give the description. Therefore, one skilled in the art would have to find for themselves that what the claimed mutant does, and this falls short of meeting the requirements of full scope of enablement. For the reasons set forth above, undue experimentation is necessary to make and use the claimed mutants encoding a protein that retains the property of interacting with cAMP-GEFII.

3) The predictability or unpredictability of the art;

The invention is highly unpredictable for the reasons set forth for factors 1 and 2 above.

4) The amount of direction or guidance presented;

5) The presence or absence of working examples; and,

6) The quantity of experimentation necessary:

The claims are directed to a mouse DNA that encodes the protein of SEQ ID NO: 1 and a mutant thereof; and a DNA sequence set forth in SEQ ID NO: 2 corresponds to protein of SEQ ID NO: 1. However, the specification provides only a generic description of how a variety of mutants can be generated (page 7), no specific guidance is provided on the generation of the mutants or fragments that demonstrate the biological activity of the full length protein or DNA sequences. There are no working examples of these variants in the specification. While the specification in Example (page 14, lines 15-22, Fig. 4), and at page 9, lines 4-16 describes and demonstrates that the full length DNA set forth in SEQ ID NO: 2 encoding the protein of SEQ ID NO: 1 is asserted to interact with cAMP-GEFII, there is no disclosure about the biological activities of the claimed mutants. Since the specification fails to provide sufficient guidance on the structure and function of the various mutants, it is necessary to have additional guidance on the identities of mutants/fragments to carry out further experimentation to assess their property of interacting with cAMP-GEFII.

7) The state of the prior art; and,

8) The relative skill of those skilled in the art:

The prior art has shown a cDNA with 5640 bp from a rat brain library, which encodes a large protein RIM2 with 1555 amino acid residues, RIM2 cDNA has 75.8% sequence identity to SEQ ID NO: 2 (see Wang's reference cited in previous office action), however, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the structure and function for various protein/ DNA products to be considered enabling for variants.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because in summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the guidance/the teaching in the specification is limited, and the outcome is unpredictable for the various modified forms, it is necessary to have additional guidance and to

carry out further experimentation to assess the property of the variants. Therefore, due to large quantity of experimentation necessary to determine an activity or property of the disclosed gene and the modified forms thereof, such that it can be determined how to use the claimed gene, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the specification fails to teach the skilled artisan how to make and use the claimed invention.

Conclusion

Claim 5 is rejected. Claims 3, 4 and 6 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must

conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
April 22, 2003

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